K011236

MAY 1 4 2001

510(k) SUMMARY

510(k) NUMBER:

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8000

CONTACT PERSON: Anil Bhalani
Director of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: April 20, 2001

NAME OF DEVICE: Implantable Clip

CLASSIFICATION NAME: Implantable Clip (21 CFR 878.4300)

TRADE NAME: Not Determined

PREDICATE DEVICES: 1. LIGACLIP™ ERCA, Ethicon, Inc.

INTENDED USE: The Applied Medical Implantable Clip is indicated for ligation of tubular structures or vessels in laparoscopic and general surgical procedures.

DEVICE DESCRIPTION: The Implantable Clip is a sterile single use device indicated for ligation of tubular structures or vessels in laparoscopic and general surgical procedures. The clip is manufactured from implant grade titanium. The clips are supplied pre-packaged in a pre-assembled cartridge loaded with 14 functional clips. The clip applier system used to deliver the clips consists of the disposable clip cartridge and a reusable handle, which provide the mechanical mechanism for storing, advancing and delivering the implantable clips. The system is designed for use with a 11mm diameter or larger trocar cannula.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the Implantable Clip included tests to analyze the jaw occlusion force of the clip appliers used with the clips discussed in this submission, leak pressure tests on vessels ligated by the clips and clip retention force of the clips. The performance and functional testing demonstrated that the Implantable Clip is substantially equivalent to the predicate devices and it introduces no new safety and effectiveness issues when used as instructed.

LIGACLIP™ is a trademark of Ethicon, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2001

Mr. Anil Bhalani
Director of Regulatory Affairs
and Clinical Programs
Applied Medical Resources, Inc.
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K011236
Trade/Device Name: Implantable Clip
Regulation Number: 878.4300
Regulatory Class: II
Product Code: FZP
Dated: April 20, 2001
Received: April 23, 2001

Dear Mr. Bhalani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Implantable Clip "Indications for Use" as required.

510(k) Number: Not assigned K011236

Device Name: Implantable Clip

Indications for Use: The Applied Medical Implantable Clip is indicated for ligation of tubular structures or vessels in laparoscopic and general surgical procedures.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *4-20-01*

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011236

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)